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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. 24-cv-09729 (RMB) (AMD)
APOTEX INC.,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), for their Complaint against Defendant Apotex Inc. ("Apotex"), allege as follows:

THE PARTIES

1. Plaintiff Novo Nordisk Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

2. Plaintiff Novo Nordisk A/S is an entity organized and existing under the laws of the Kingdom of Denmark, having its principal place of business at Novo Allé, 2880 Bagsvaerd Denmark. Novo Nordisk Inc. is an indirect, wholly owned subsidiary of Novo Nordisk A/S.

3. On information and belief, Apotex is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, North York, Toronto, M9L 1T9. On information and belief, Apotex is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

NATURE OF THE ACTION

4. This action arises under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. § 271(a), (b), (c), and (e), arising from Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 219837 ("Apotex's ANDA") to the United States Food and Drug Administration ("FDA"), by which Apotex seeks approval of a generic version of Novo Nordisk's pharmaceutical product RYBELSUS® Formulation R1 (hereinafter "RYBELSUS®") (semaglutide) tablets prior to the expiration of United States Patent Nos. 8,129,343 ("the '343 Patent"); 8,536,122 ("the '122 Patent"); 9,278,123 ("the '123 Patent"); 10,086,047 ("the '047 Patent"); 10,278,923 ("the '923 Patent"); 10,933,120 ("the '120 Patent"); 10,960,052 ("the '052 Patent"); 11,382,957 ("the '957 Patent"); 11,759,501 ("the '501 Patent"); 11,759,502 ("the '502 Patent"); and 11,759,503 ("the '503 Patent") (collectively, the "Asserted Patents"), attached hereto as Exhibits 1–11, which cover, *inter alia*, RYBELSUS® (semaglutide) tablets and/or their use.

5. Novo Nordisk A/S is the owner of all rights, title, and interest in the Asserted Patents.

6. Novo Nordisk Inc. is the holder of New Drug Application ("NDA") No. 213051 for RYBELSUS® (semaglutide) tablets, 3 mg, 7 mg, and 14 mg, which Novo Nordisk Inc. sells under the trade name RYBELSUS®. Novo Nordisk Inc. holds the exclusive right to sell, distribute, and market RYBELSUS® (semaglutide) tablets in the United States.

7. The Asserted Patents are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with RYBELSUS® and the related NDA.

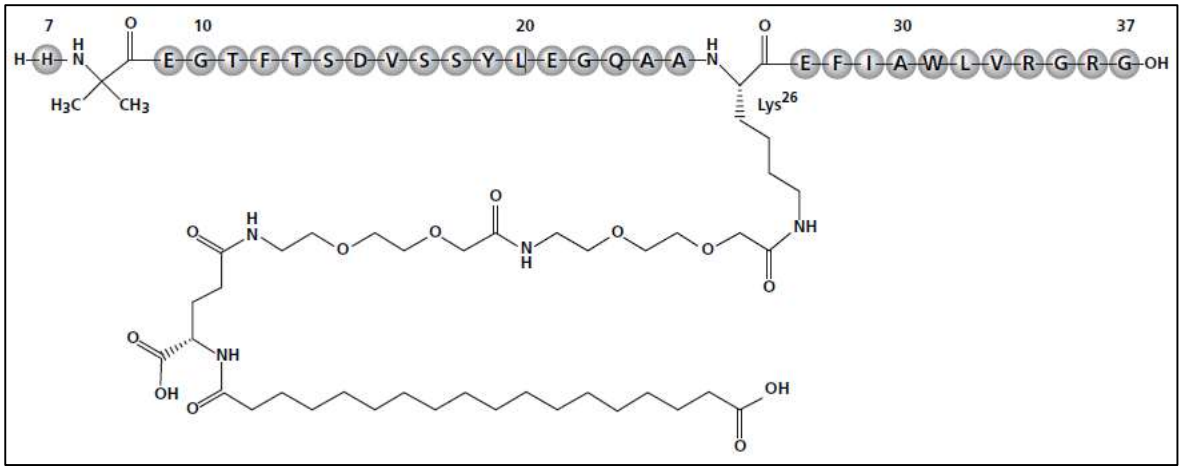
NOVO NORDISK'S RYBELSUS®

8. The Prescribing Information for RYBELSUS® ("RYBELSUS® Label") states that "RYBELSUS is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

9. RYBELSUS® is to be administered once daily by oral tablet.

10. The RYBELSUS® Label further instructs that RYBELSUS® should be administered once daily "on an empty stomach in the morning with . . . up to 4 ounces of water[]" and "at least 30 minutes before eating food, drinking beverages, or taking other oral medications," according to a dose escalation schedule that includes an initiating dosage at 3 mg of semaglutide for 30 days, and then increasing the dosage to 7 mg once daily for 30 days. If additional glycemic control is needed, the dosage may be increased to 14 mg.

11. The active ingredient in RYBELSUS® is semaglutide and its structure is:



12. The RYBELSUS® Label further teaches that the half-life of semaglutide is approximately 1 week.

13. RYBELSUS® is a tablet for oral use. Each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide, and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

APOTEX'S ANDA AND PARAGRAPH IV CERTIFICATION

14. On information and belief, Apotex submitted Apotex's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and/or sell a generic version of semaglutide tablets (formulation R1), 3 mg, 7 mg, and 14 mg, for oral administration pursuant to Apotex's ANDA ("Apotex's ANDA Product").

15. On information and belief, following any FDA approval of Apotex's ANDA, Apotex will manufacture, market, distribute, and sell Apotex's ANDA Product throughout the United States, including within New Jersey.

16. On information and belief, Apotex's ANDA refers to and relies upon RYBELSUS®'s NDA and contains data that, according to Apotex, demonstrate the bioequivalence of Apotex's ANDA Product and RYBELSUS®.

17. On information and belief, Apotex made and included in Apotex's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Asserted Patents are invalid and/or not infringed.

18. Novo Nordisk received written notice of Apotex's ANDA and Paragraph IV Certification as to the Asserted Patents, dated August 29, 2024 ("August 29, 2024 Notice Letter") and November 21, 2024 ("November 21, 2024 Notice Letter") (collectively, the "Notice Letters"). Novo Nordisk received with each Notice Letter an enclosed statement that is required to state all the factual and legal bases for Apotex's contention that the commercial manufacture, use, or sale of Apotex's ANDA Product allegedly will not infringe any valid claim of the Asserted Patents and/or that the claims of the Asserted Patents allegedly are invalid and/or unenforceable (the "August 29, 2024 Detailed Statement" and the "November 21, 2024 Detailed Statement"). Apotex's Detailed Statements, however, do not allege or provide any factual or legal bases to assert that the Asserted Patents are unenforceable.

19. This action was commenced within 45 days of receipt of the August 29, 2024 Notice Letter.

20. This First Amended Complaint is being filed within 45 days of receipt of the November 21, 2024 Notice Letter.

21. Apotex has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by filing Apotex's ANDA with a Paragraph IV Certification and seeking FDA

approval of Apotex's ANDA before the expiration of the Asserted Patents, including any extensions thereof.

22. Apotex has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by filing Apotex's ANDA, including any amendments or supplements thereof, seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product before the expiration of the Asserted Patents, including any extensions thereof. Apotex will infringe one or more claims of the Asserted Patents under 35 U.S.C. § 271(a), (b), and/or (c) should Apotex engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, and/or importation into the United States of Apotex's ANDA Product before the expiration of the Asserted Patents or any extensions thereof.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

24. On information and belief, Apotex intends to commercially manufacture, use, and sell the ANDA Product upon receiving FDA approval. On information and belief, if and when FDA approves the ANDA, the ANDA Product would, among other things, be marketed, distributed and sold in New Jersey, and/or prescribed by physicians practicing within this District and/or dispensed by pharmacies located within this District, all of which would have a substantial effect on New Jersey. By filing the ANDA, Apotex has made clear that it intends to use its distribution channels to direct sales of the ANDA Product into New Jersey.

25. This Court has personal jurisdiction over Defendant Apotex by virtue of, *inter alia*, its presence in New Jersey; having conducted business in New Jersey; having derived revenue from conducting business in New Jersey; previously consenting to personal jurisdiction in this

Court (*see, e.g.*, *Amgen Inc. v. Apotex Inc.*, No. 22-cv-03827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc.*, No. 22-cv-00322 (D.N.J.); *Takeda Pharms. Am., Inc. v. Apotex Inc*., No. 21-12998 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 19-05806 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 18-16395 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-03387 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. v. Apotex Inc*., No. 17-05278 (D.N.J.); *AstraZeneca AB v. Apotex Corp.*, No. 15-08492 (D.N.J.); *Bausch & Lomb Inc. v. Apotex Inc*., No. 15-03879 (D.N.J.); *Novartis Pharm. Corp. v. Apotex Inc.*, No. 15-03634 (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc.*, No. 15-02384 (D.N.J.); *Patheon Softgels Inc. v. Apotex Inc.*, No. 17-13819 (D.N.J.); *Dexcel Pharma Techs. Ltd. v. Apotex Corp.*, No. 17-02423 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. v. Apotex Inc.*, No. 18-11350 (D.N.J.)); and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, *Apotex Inc. v. Shire LLC*, No. 08-03598 (D.N.J.); *Apotex Inc. v. Pharm. Res., Inc*., No. 06-01153 (D.N.J.)).

26. On information and belief, Apotex intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Apotex's ANDA Product, directly or indirectly, throughout the United States and in this District. Apotex's filing of Apotex's ANDA confirms this intention and further subjects Apotex to the specific personal jurisdiction of this Court.

27. Apotex is a foreign corporation not resident in the United States. Thus, venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

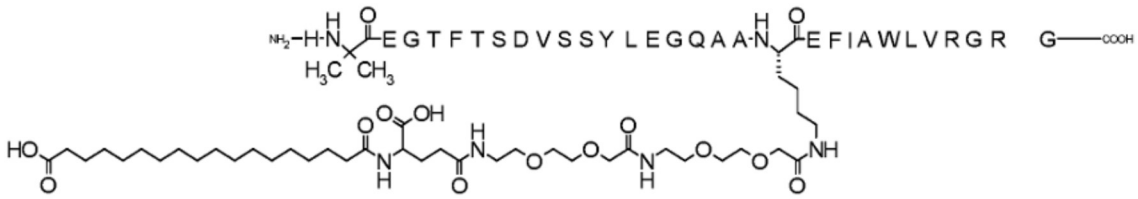
U.S. Patent No. 8,129,343

28. The allegations above are incorporated herein by reference.

29. Novo Nordisk A/S is the owner of all rights, title, and interest in the '343 Patent, entitled "Acylated GLP-1 Compounds." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '343 Patent on March 6, 2012. The '343 Patent names

Jesper Lau, Paw Bloch, and Thomas Kruse Hansen as inventors. All named inventors assigned the '343 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '343 Patent and sue for infringement thereof. A true and correct copy of the '343 Patent is attached to this Complaint as Exhibit 1.

30. The '343 Patent claims a compound of the following structure, as well as a pharmaceutical composition comprising the same compound with the following structure and a pharmaceutically acceptable excipient:



31. The structure above and the claimed compound of the '343 Patent is semaglutide.

U.S. Patent No. 8,536,122

32. The allegations above are incorporated herein by reference.

33. Novo Nordisk A/S is the owner of all rights, title, and interest in the '122 Patent, entitled "Acylated GLP-1 Compounds." The USPTO duly and legally issued the '122 Patent on September 17, 2013. The '122 Patent names Jesper Lau, Florencio Zaragoza Doerwald, Paw Bloch, and Thomas Kruse Hansen as inventors. All named inventors assigned the '122 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '122 Patent and sue for infringement thereof. A true and correct copy of the '122 Patent is attached to this Complaint as Exhibit 2. The '122 Patent claims compounds of GLP-1 analogs and pharmaceutical compositions comprising a GLP-1 analog.

U.S. Patent No. 9,278,123

34. The allegations above are incorporated herein by reference.

35. Novo Nordisk A/S is the owner of all rights, title, and interest in the '123 Patent, entitled "Solid Compositions Comprising a GLP-1 Agonist and a Salt of N-(8-(2-Hydroxybenzoyl)Amino)Caprylic Acid." The USPTO duly and legally issued the '123 Patent on March 8, 2016. The '123 Patent names Per Sauerberg, Simon Bjerredgaard, and Flemming Seier Nielsen as inventors. All named inventors assigned the '123 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '123 Patent and sue for infringement thereof. A true and correct copy of the '123 Patent is attached to this Complaint as Exhibit 3.

36. The '123 Patent claims, among others, a solid composition for oral administration, comprising semaglutide and 0.8-1.3 mmol of a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid.

U.S. Patent No. 10,086,047

37. The allegations above are incorporated herein by reference.

38. Novo Nordisk A/S is the owner of all rights, title, and interest in the '047 Patent, entitled "Solid Compositions Comprising a GLP-1 Agonist and a Salt of N-(8-(2-Hydroxybenzoyl)Amino)Caprylic Acid." The USPTO duly and legally issued the '047 Patent on October 2, 2018. The '047 Patent names Per Sauerberg, Simon Bjerredgaard, and Flemming Seier Nielsen as inventors. All named inventors assigned the '047 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '047 Patent and sue for infringement thereof. A true and correct copy of the '047 Patent is attached to this Complaint as Exhibit 4.

39. The '047 Patent claims, among others, a solid composition for oral administration, comprising 0.5 to 2.5 μmol semaglutide and 0.8 to 1.3 mmol of a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid, wherein the composition has surface eroding or co-release properties, and a disintegration time of 7-15 minutes.

U.S. Patent No. 10,278,923

40. The allegations above are incorporated herein by reference.

41. Novo Nordisk A/S is the owner of all rights, title, and interest in the '923 Patent, entitled "Oral Dosing of GLP-1 Compounds." The USPTO duly and legally issued the '923 Patent on May 7, 2019. The '923 Patent names Flemming Seier Nielsen and Per Sauerberg as inventors. All named inventors assigned the '923 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '923 Patent and sue for infringement thereof. A true and correct copy of the '923 Patent is attached to this Complaint as Exhibit 5.

42. The '923 Patent claims, among others, a method for treating diabetes and/or obesity in a subject in need of such treatment, comprising orally administering to said subject a therapeutically effective amount of a solid oral dosage form composition comprising a GLP-1 peptide that is from a group including semaglutide and has a plasma half-life in humans of at least 60 hours, an enhancer that is a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid, and wherein the composition is administered such that the ratio between the plasma half-life in days in humans of the GLP-1 peptide and the dosing interval in days of said composition is more than 2:1.

U.S. Patent No. 10,933,120

43. The allegations above are incorporated herein by reference.

44. Novo Nordisk A/S is the owner of all rights, title, and interest in the '120 Patent, entitled "Compositions of GLP-1 Peptides and Preparation Thereof." The USPTO duly and legally issued the '120 Patent on March 2, 2021. The '120 Patent names Thomas Vilhelmsen, Helle Eliasen, and Tue Hansen as inventors. All named inventors assigned the '120 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '120 Patent and sue for infringement thereof. A true and correct copy of the '120 Patent is attached to this Complaint as Exhibit 6.

45. The '120 Patent claims, among others, a solid dosage pharmaceutical composition comprising: a first type of granule or granules comprising sodium N-(8-(2-hydroxybenzoyl)amino)caprylic acid (SNAC), lubricant, and no GLP-1 peptide, wherein the SNAC is at least 75% (w/w), and wherein the lubricant is less than 10% (w/w), a second type of granule or granules comprising semaglutide, filler, binder, and no SNAC, where the semaglutide is 2 to 40% (w/w), the filler is at least 15% (w/w), and the binder is less than 40% (w/w), and where the composition is a tablet weighing between 150 to 1000 mg.

U.S. Patent No. 10,960,052

46. The allegations above are incorporated herein by reference.

47. Novo Nordisk A/S is the owner of all rights, title, and interest in the '052 Patent, entitled "Solid Compositions Comprising a GLP-1 Agonist and a Salt of N-(8-(2-Hydroxybenzoyl)Amino)Caprylic Acid." The USPTO duly and legally issued the '052 Patent on March 30, 2021. The '052 Patent names Per Sauerberg, Simon Bjerredgaard, and Flemming Seier Nielsen as inventors. All named inventors assigned the '052 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '052 Patent and sue for infringement thereof. A true and correct copy of the '052 Patent is attached to this Complaint as Exhibit 7.

48. The '052 Patent claims, among others, a solid composition for oral administration comprising a GLP-1 agonist, a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid, magnesium stearate, povidone, and microcrystalline cellulose, wherein the GLP-1 agonist is semaglutide, wherein the composition comprises at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid.

U.S. Patent No. 11,382,957

49. The allegations above are incorporated herein by reference.

50. Novo Nordisk A/S is the owner of all rights, title, and interest in the '957 Patent, entitled "Solid Compositions Comprising a GLP-1 Agonist and a Salt of N-(8-(2-Hydroxybenzoyl)Amino)Caprylic Acid." The USPTO duly and legally issued the '957 Patent on July 12, 2022. The '957 Patent names Per Sauerberg, Simon Bjerredgaard, and Flemming Seier Nielsen as inventors. All named inventors assigned the '957 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '957 Patent and sue for infringement thereof. A true and correct copy of the '957 Patent is attached to this Complaint as Exhibit 8.

51. The '957 Patent claims, among others, a solid composition for oral administration comprising a GLP-1 agonist, a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid, and at least one excipient selected from the group consisting of a lubricant, binder, and filler, wherein the GLP-1 agonist is semaglutide, and wherein the composition comprises at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid.

U.S. Patent No. 11,759,501

52. The allegations above are incorporated herein by reference.

53. Novo Nordisk A/S is the owner of all rights, title, and interest in the '501 Patent, entitled "Compositions of GLP-1 Peptides and Preparation Thereof." The USPTO duly and legally issued the '501 Patent on September 19, 2023. The '501 Patent names Thomas Vilhelmsen, Helle Eliasen, and Tue Hansen as inventors. All named inventors assigned the '501 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '501 Patent and sue for infringement thereof. A true and correct copy of the '501 Patent is attached to this Complaint as Exhibit 9.

54. The '501 Patent claims, among others, a solid dosage pharmaceutical composition comprising (1) semaglutide and (2) a granule, wherein the granule comprises a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid (salt of NAC), a lubricant, and no semaglutide, wherein the

salt of NAC is at least 75% (w/w) of the granule, and wherein the lubricant is less than 10% (w/w) of the granule.

U.S. Patent No. 11,759,502

55. The allegations above are incorporated herein by reference.

56. Novo Nordisk A/S is the owner of all rights, title, and interest in the '502 Patent, entitled "Compositions of GLP-1 Peptides and Preparation Thereof." The USPTO duly and legally issued the '502 Patent on September 19, 2023. The '502 Patent names Thomas Vilhelmsen, Helle Eliasen, and Tue Hansen as inventors. All named inventors assigned the '502 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '502 Patent and sue for infringement thereof. A true and correct copy of the '502 Patent is attached to this Complaint as Exhibit 10.

57. The '502 Patent claims, among others, a solid dosage pharmaceutical composition comprising (1) a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid (salt of NAC) and (2) a granule, wherein the granule comprises semaglutide, a binder, a filler, and no salt of NAC; wherein the filler is at least 15% (w/w) of the granule; and wherein the binder is less than 40% (w/w) of the granule.

U.S. Patent No. 11,759,503

58. The allegations above are incorporated herein by reference.

59. Novo Nordisk A/S is the owner of all rights, title, and interest in the '503 Patent, entitled "Compositions of GLP-1 Peptides and Preparation Thereof." The USPTO duly and legally issued the '503 Patent on September 19, 2023. The '503 Patent names Thomas Vilhelmsen, Helle Eliasen, and Tue Hansen as inventors. All named inventors assigned the '503 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '503 Patent and sue for infringement thereof. A true and correct copy of the '503 Patent is attached to this Complaint as Exhibit 11.

60. The ’503 Patent claims, among others, a solid dosage pharmaceutical composition comprising (a) a first type of granules comprising at least 75% (w/w) of sodium N-(8-(2-hydroxybenzoyl)amino)caprylic acid (SNAC) and less than 10% (w/w) of a lubricant and (b) a second type of granules comprising semaglutide, at least 15% (w/w) of a filler, and less than 40% (w/w) of a binder.

COUNT I
(INFRINGEMENT OF THE ’343 PATENT)

61. The allegations above are incorporated herein by reference.

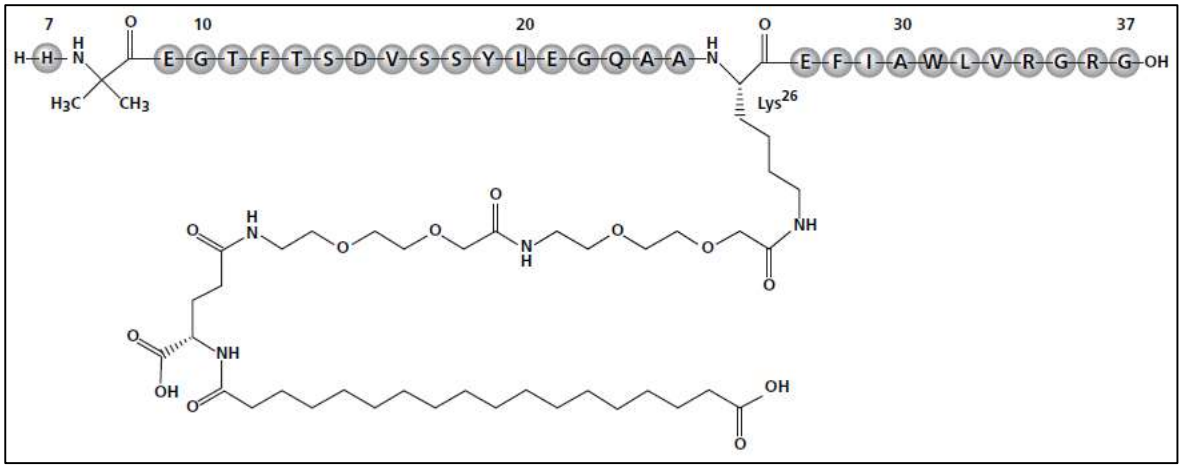
62. Apotex submitted Apotex’s ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex’s ANDA Product before the expiration of the ’343 Patent, including any extensions thereof.

63. The August 29, 2024 Notice Letter states that Apotex’s ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex’s ANDA Product before the expiration of the ’343 Patent. The August 29, 2024 Notice Letter represents that Apotex’s ANDA was submitted with a Paragraph IV Certification that the ’343 Patent is “invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex’s ANDA.”

64. Apotex has actual knowledge of the ’343 Patent.

65. The RYBELSUS® Label states that the active ingredient in RYBELSUS® is semaglutide and that RYBELSUS® contains inactive ingredients.

66. The RYBELSUS® Label states that the structure of semaglutide is:



67. RYBELSUS® is covered by at least claim 1 of the ’343 Patent.

68. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the ’343 Patent.

69. The ’343 Patent is listed in the Orange Book for RYBELSUS®.

70. On information and belief, Apotex’s ANDA essentially copies the RYBELSUS® Label and active ingredient, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex’s ANDA Product is identical to that in RYBELSUS®.

71. On information and belief, Apotex’s ANDA will purport to show that Apotex’s ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex’s ANDA Product is identical to that in RYBELSUS®.

72. On information and belief, Apotex’s ANDA will purport to show that Apotex’s ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex’s ANDA Product is identical to that in RYBELSUS®.

73. On information and belief, if Apotex’s ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex’s ANDA Product in a manner that would infringe at least claim 1 of the ’343 Patent.

74. Apotex has infringed at least claim 1 of the '343 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '343 Patent, before the expiration of the '343 Patent.

75. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '343 Patent under 35 U.S.C. § 271(a).

76. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

77. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '343 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

78. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '343 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '343 Patent under 35 U.S.C. § 271(a).

79. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '343 Patent, including any extensions thereof, or any later expiration of extensions, adjustments, and exclusivities for the '343 Patent to which Novo Nordisk becomes entitled.

80. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '343 Patent. Pursuant to 35 U.S.C. §§ 283 and 271(e)(4)(B), Novo Nordisk

is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

81. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '343 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

82. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '343 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT II
(INFRINGEMENT OF THE '122 PATENT)

83. The allegations above are incorporated herein by reference.

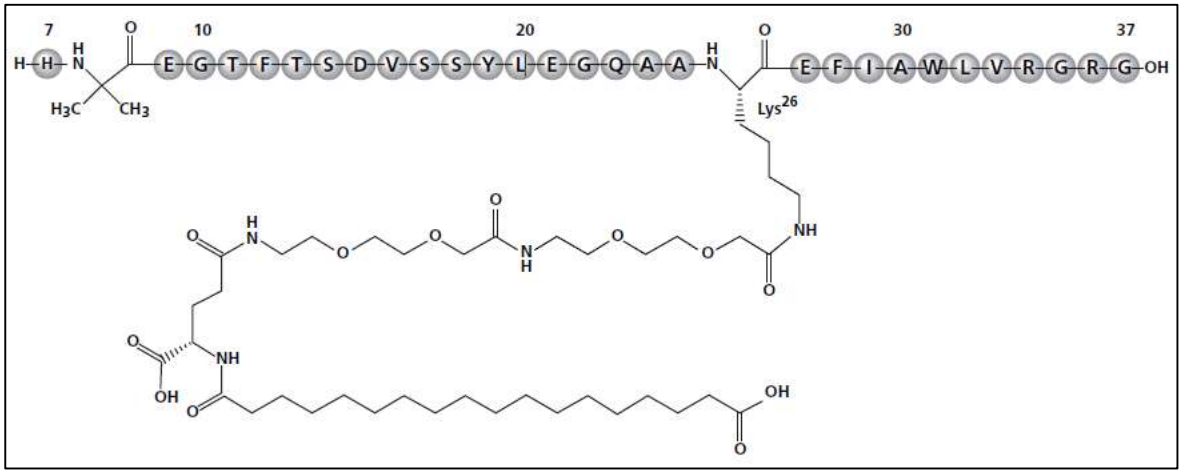
84. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '122 Patent, including any extensions thereof.

85. The November 21, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '122 Patent. The November 21, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '122 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation of the drug products described in Apotex's ANDA No. 219837."

86. Apotex has actual knowledge of the '122 Patent.

87. The RYBELSUS® Label states that the active ingredient in RYBELSUS® is semaglutide and that RYBELSUS® contains inactive ingredients.

88. The RYBELSUS® Label states that the structure of semaglutide is:



89. RYBELSUS® is covered by at least claim 1 of the '122 Patent.

90. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '122 Patent.

91. The '122 Patent is listed in the Orange Book for RYBELSUS®.

92. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and active ingredient, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

93. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

94. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

95. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '122 Patent.

96. Apotex has infringed at least claim 1 of the '122 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '122 Patent, before the expiration of the '122 Patent.

97. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '122 Patent under 35 U.S.C. § 271(a).

98. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

99. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '122 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

100. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '122 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '122 Patent under 35 U.S.C. § 271(a).

101. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '122 Patent, including any extensions thereof, or any later expiration of

extensions, adjustments, and exclusivities for the '122 Patent to which Novo Nordisk becomes entitled.

102. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing, actively inducing the infringement of, or contributing to the infringement of at least claim 1 of the '122 Patent. Pursuant to 35 U.S.C. §§ 283 and 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

103. On information and belief, Apotex's November 21, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '122 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

104. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '122 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT III
(INFRINGEMENT OF THE '123 PATENT)

105. The allegations above are incorporated herein by reference.

106. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '123 Patent, including any extensions thereof.

107. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '123 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '123 Patent is "invalid, unenforceable,

and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

108. Apotex has actual knowledge of the '123 Patent.

109. The RYBELSUS® Label states that each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

110. The RYBELSUS® Label states that the active ingredient in RYBELSUS® is semaglutide.

111. RYBELSUS® is covered by at least claim 1 of the '123 Patent.

112. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '123 Patent.

113. The '123 Patent is listed in the Orange Book for RYBELSUS®.

114. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

115. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

116. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

117. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '123 Patent.

118. Apotex has infringed at least claim 1 of the '123 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '123 Patent, before the expiration of the '123 Patent.

119. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '123 Patent under 35 U.S.C. § 271(a).

120. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

121. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '123 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

122. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '123 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '123 Patent under 35 U.S.C. § 271(a).

123. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '123 Patent or any later expiration of extensions, adjustments, and exclusivities for the '123 Patent to which Novo Nordisk becomes entitled.

124. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '123 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

125. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '123 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

126. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '123 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT IV
(INFRINGEMENT OF THE '047 PATENT)

127. The allegations above are incorporated herein by reference.

128. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '047 Patent, and any extensions thereof.

129. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '047 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '047 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

130. Apotex has actual knowledge of the '047 Patent.

131. The RYBELSUS® Label states that RYBELSUS® is a tablet for oral use.

132. The RYBELSUS® Label states that each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

133. The RYBELSUS® Label states that the active ingredient in RYBELSUS® is semaglutide.

134. Thus, RYBELSUS® is covered by at least claim 1 of the '047 Patent.

135. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '047 Patent.

136. The '047 Patent is listed in the Orange Book for RYBELSUS®.

137. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

138. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

139. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

140. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '047 Patent.

141. Apotex has infringed at least claim 1 of the '047 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '047 Patent, before the expiration of the '047 Patent.

142. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '047 Patent under 35 U.S.C. § 271(a).

143. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

144. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '047 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

145. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '047 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '047 Patent under 35 U.S.C. § 271(a).

146. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '047 Patent or any later expiration of extensions, adjustments, and exclusivities for the '047 Patent to which Novo Nordisk becomes entitled.

147. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '047 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B),

Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

148. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '047 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

149. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '047 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT V
(INFRINGEMENT OF THE '923 PATENT)

150. The allegations above are incorporated herein by reference.

151. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '923 Patent, and any extensions thereof.

152. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '923 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '923 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

153. Apotex has actual knowledge of the '923 Patent.

154. On information and belief, Apotex's ANDA Product is covered by at least claim 14 of the '923 Patent, and Apotex has therefore infringed the '923 Patent.

155. The RYBELSUS® Label instructs physicians, prescribers, and/or patients that RYBELSUS® is to be administered once daily by oral tablet.

156. The RYBELSUS® Label instructs physicians, prescribers, and/or patients that "RYBELSUS is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

157. The RYBELSUS® Label instructs physicians, prescribers, and/or patients to administer RYBELSUS® once daily "on an empty stomach in the morning with . . . up to 4 ounces of water[]" and "at least 30 minutes before eating food, drinking beverages, or taking other oral medications," according to a dose escalation schedule that includes an initiating dosage at 3 mg of semaglutide once daily for 30 days, and then increasing the dosage to 7 mg once daily for 30 days. If additional glycemic control is needed, the dosage may be increased to 14 mg once daily.

158. The RYBELSUS® Label further teaches that the half-life of semaglutide is approximately 1 week.

159. The use of RYBELSUS® is covered by at least claim 14 of the '923 Patent.

160. Thus, the use of any corresponding generic semaglutide tablet based on RYBELSUS® are covered by at least claim 14 of the '923 Patent.

161. The '923 Patent is listed in the Orange Book for RYBELSUS®.

162. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

163. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

164. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

165. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe, induce infringement, and contribute to infringement of at least claim 14 of the '923 Patent.

166. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label, including as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claim 14 of the '923 Patent.

167. On information and belief, if Apotex's ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Apotex's ANDA Product and thereby infringe at least claim 14 of the '923 Patent.

168. RYBELSUS® and any corresponding generic semaglutide tablet are not a staple article of commerce and have no substantial approved uses that do not infringe at least claim 14 of the '923 Patent. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 14 of the '923 Patent.

169. Apotex has infringed at least claim 14 of the '923 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for

Apotex's ANDA Product, which is covered by at least claim 14 of the '923 Patent, before the expiration of the '923 Patent.

170. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe or contribute to or induce infringement of at least claim 14 of the '923 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

171. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

172. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 14 of the '923 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

173. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 14 of the '923 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '923 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

174. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '923 Patent or any later expiration of extensions, adjustments, and exclusivities for the '923 Patent to which Novo Nordisk becomes entitled.

175. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing, actively inducing the infringement of, or contributing to the infringement of at least claim 14 of the '923 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

176. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '923 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

177. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '923 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT VI
(INFRINGEMENT OF THE '120 PATENT)

178. The allegations above are incorporated herein by reference.

179. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '120 Patent, and any extensions thereof.

180. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '120 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '120 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

181. Apotex has actual knowledge of the '120 Patent.

182. The RYBELSUS® Label states that RYBELSUS® is to be administered once daily by oral tablet.

183. RYBELSUS® is a tablet for oral use. Each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive

ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

184. The RYBELSUS® composition is covered by at least claim 1 of the '120 Patent.

185. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '120 Patent.

186. The '120 Patent is listed in the Orange Book for RYBELSUS®.

187. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

188. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

189. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

190. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '120 Patent.

191. Apotex has infringed at least claim 1 of the '120 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '120 Patent, before the expiration of the '120 Patent.

192. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '120 Patent under 35 U.S.C. § 271(a).

193. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

194. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '120 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

195. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '120 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '120 Patent under 35 U.S.C. § 271(a).

196. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '120 Patent or any later expiration of extensions, adjustments, and exclusivities for the '120 Patent to which Novo Nordisk becomes entitled.

197. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '120 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

198. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and

validity of the '120 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

199. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '120 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT VII
(INFRINGEMENT OF THE '052 PATENT)

200. The allegations above are incorporated herein by reference.

201. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '052 Patent, including any extensions thereof.

202. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '052 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '052 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

203. Apotex has actual knowledge of the '052 Patent.

204. The RYBELSUS® Label states that RYBELSUS® is a tablet for oral use.

205. The RYBELSUS® Label states that each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

206. The RYBELSUS® Label states that the active ingredient in RYBELSUS® is semaglutide.

207. The RYBELSUS® composition is covered by at least claim 1 of the '052 Patent.

208. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '052 Patent.

209. The '052 Patent is listed in the Orange Book for RYBELSUS®.

210. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

211. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

212. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

213. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '052 Patent.

214. Apotex has infringed at least claim 1 of the '052 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '052 Patent, before the expiration of the '052 Patent.

215. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '052 Patent under 35 U.S.C. § 271(a).

216. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

217. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '052 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

218. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '052 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '052 Patent under 35 U.S.C. § 271(a).

219. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '052 Patent or any later expiration of extensions, adjustments, and exclusivities for the '052 Patent to which Novo Nordisk becomes entitled.

220. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '052 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

221. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and

validity of the '052 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

222. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '052 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT VIII
(INFRINGEMENT OF THE '957 PATENT)

223. The allegations above are incorporated herein by reference.

224. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '957 Patent, including any extensions thereof.

225. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '957 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '957 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

226. Apotex has actual knowledge of the '957 Patent.

227. The RYBELSUS® Label states that RYBELSUS® is a tablet for oral use.

228. The RYBELSUS® Label states that each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

229. The RYBELSUS® Label states that the active ingredient in RYBELSUS® is semaglutide.

230. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '957 Patent.

231. The '957 Patent is listed in the Orange Book for RYBELSUS®.

232. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

233. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

234. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

235. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '957 Patent.

236. Apotex has infringed at least claim 1 of the '957 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '957 Patent, before the expiration of the '957 Patent.

237. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '957 Patent under 35 U.S.C. § 271(a).

238. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

239. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '957 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

240. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '957 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '957 Patent under 35 U.S.C. § 271(a).

241. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '957 Patent or any later expiration of extensions, adjustments, and exclusivities for the '957 Patent to which Novo Nordisk becomes entitled.

242. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '957 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

243. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '957 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

244. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '957 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT IX
(INFRINGEMENT OF THE '501 PATENT)

245. The allegations above are incorporated herein by reference.

246. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '501 Patent, including any extensions thereof.

247. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '501 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '501 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

248. Apotex has actual knowledge of the '501 Patent.

249. The RYBELSUS® Label states that RYBELSUS® is to be administered once daily by oral tablet.

250. RYBELSUS® is a tablet for oral use. Each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

251. The RYBELSUS® composition is covered by at least claim 1 of the '501 Patent.

252. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '501 Patent.

253. The '501 Patent is listed in the Orange Book for RYBELSUS®.

254. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

255. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

256. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

257. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '501 Patent.

258. Apotex has infringed at least claim 1 of the '501 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '501 Patent, before the expiration of the '501 Patent.

259. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '501 Patent under 35 U.S.C. § 271(a).

260. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

261. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '501 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

262. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '501 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '501 Patent under 35 U.S.C. § 271(a).

263. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '501 Patent or any later expiration of extensions, adjustments, and exclusivities for the '501 Patent to which Novo Nordisk becomes entitled.

264. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '501 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

265. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '501 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

266. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '501 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT X
(INFRINGEMENT OF THE '502 PATENT)

267. The allegations above are incorporated herein by reference.

268. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '502 Patent, including any extensions thereof.

269. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '502 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '502 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

270. Apotex has actual knowledge of the '502 Patent.

271. The RYBELSUS® Label states that RYBELSUS® is to be administered once daily by oral tablet.

272. RYBELSUS® is a tablet for oral use. Each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

273. The RYBELSUS® composition is covered by at least claim 1 of the '502 Patent.

274. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '502 Patent.

275. The '502 Patent is listed in the Orange Book for RYBELSUS®.

276. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

277. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

278. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

279. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '502 Patent.

280. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '502 Patent under 35 U.S.C. § 271(a).

281. Apotex has infringed at least claim 1 of the '502 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '502 Patent, before the expiration of the '502 Patent.

282. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

283. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '502 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

284. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '502 Patent or any later expiration of extensions, adjustments, and exclusivities for the '502 Patent to which Novo Nordisk becomes entitled.

285. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '502 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '502 Patent under 35 U.S.C. § 271(a).

286. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '502 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

287. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '502 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

288. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '502 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT XI
(INFRINGEMENT OF THE '503 PATENT)

289. The allegations above are incorporated herein by reference.

290. Apotex submitted Apotex's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '503 Patent, and any extensions thereof.

291. The August 29, 2024 Notice Letter states that Apotex's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Apotex's ANDA Product before the expiration of the '503 Patent. The August 29, 2024 Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the '503 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Apotex's ANDA."

292. Apotex has actual knowledge of the '503 Patent.

293. The RYBELSUS® Label states that RYBELSUS® is to be administered once daily by oral tablet.

294. RYBELSUS® is a tablet for oral use. Each tablet of RYBELSUS® contains 3 mg, 7 mg, or 14 mg of semaglutide; and the RYBELSUS® Label lists the following inactive ingredients: "magnesium stearate, microcrystalline cellulose, povidone and salcaprozate sodium (SNAC)."

295. The RYBELSUS® composition is covered by at least claim 1 of the '503 Patent.

296. Thus, RYBELSUS® and any corresponding generic semaglutide tablet are covered by at least claim 1 of the '503 Patent.

297. The '503 Patent is listed in the Orange Book for RYBELSUS®.

298. On information and belief, Apotex's ANDA essentially copies the RYBELSUS® Label and composition, including as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(5), 314.94(a)(8)(iv), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

299. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product has the same strength as RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(6), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

300. On information and belief, Apotex's ANDA will purport to show that Apotex's ANDA Product is bioequivalent to RYBELSUS®, *see* 21 C.F.R. § 314.94(a)(7), and as such, the composition in Apotex's ANDA Product is identical to that in RYBELSUS®.

301. On information and belief, if Apotex's ANDA is approved, Apotex will make, use, offer for sale, sell, or import Apotex's ANDA Product in a manner that would infringe at least claim 1 of the '503 Patent.

302. Apotex has infringed at least claim 1 of the '503 Patent under 35 U.S.C. § 271(e)(2)(A) by its submission of Apotex's ANDA to FDA seeking to obtain approval for Apotex's ANDA Product, which is covered by at least claim 1 of the '503 Patent, before the expiration of the '503 Patent.

303. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Apotex's ANDA would directly infringe at least claim 1 of the '503 Patent under 35 U.S.C. § 271(a).

304. Novo Nordisk seeks an order requiring that Apotex amend its Paragraph IV Certification in Apotex's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3).

305. Novo Nordisk seeks an order declaring that Apotex has infringed at least claim 1 of the '503 Patent by submitting Apotex's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

306. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Apotex's ANDA be a date that is not earlier than the expiration of the '503 Patent or any later expiration of extensions, adjustments, and exclusivities for the '503 Patent to which Novo Nordisk becomes entitled.

307. Novo Nordisk seeks an order declaring that Apotex will infringe at least claim 1 of the '503 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Apotex's ANDA Product before the expiration of the '503 Patent under 35 U.S.C. § 271(a).

308. Novo Nordisk will be irreparably harmed if Apotex is not enjoined from infringing at least claim 1 of the '503 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

309. On information and belief, Apotex's August 29, 2024 Detailed Statement purportedly setting forth the factual and legal bases for its opinion regarding infringement and validity of the '503 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

310. To the extent Apotex commercializes Apotex's ANDA Product prior to the expiration of the '503 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in their favor against Apotex and grant the following relief:

A. An adjudication that Apotex has infringed one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA Apotex's ANDA, including any amendments or supplements thereof, to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Apotex's ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

B. A judgment declaring that Apotex will directly infringe, contribute to the direct infringement of, and/or induce the direct infringement of one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States Apotex's ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

C. An order requiring that Apotex amend its Paragraph IV certification as to the Asserted Patents to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(i)(A)(3);

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Apotex's ANDA for Apotex's ANDA Product be a date that is not earlier than the latest date of the expiration of the Asserted Patents or any later period of exclusivity to which Plaintiffs are or may become entitled;

E. A permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the Asserted Patents or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in Apotex's ANDA;

F. An order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the Asserted Patents, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of Apotex's ANDA Product;

G. An assessment of pre-judgment and post-judgment interest and costs against Apotex, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

H. An award to Plaintiffs of their attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. Such other and further relief as this Court may deem just and proper.

Dated: December 11, 2024

/s/*Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is this action is related to the following pending litigations:

Novo Nordisk A/S v. Mylan Pharmaceuticals Inc., No. 23-101-CFC (D. Del.)

Novo Nordisk A/S v. Sun Pharmaceuticals Industries, Ltd., No. 23-1459-CFC (D. Del.)

Novo Nordisk Inc. et al. v. Rio Biopharmaceuticals, Inc. et al., No. 22-294-CFC (D. Del.)

In re: Ozempic (Semaglutide) Patent Litigation, MDL No. 22-MD-3038-CFC (D. Del.)

The '343 Patent has been asserted in the above-captioned matters against each of the named defendants, all believed to be unrelated to the Defendants named herein.

I hereby certify that, to the best of my knowledge, other than the above-listed proceedings, the matter in controversy is not the subject of or related to any other pending litigations in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiff that should be joined to this action.

Dated: December 11, 2024

/s/*Liza M. Walsh*

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: December 11, 2024

/s/*Liza M. Walsh*

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